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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,228	11/14/2003	Luigi Grasso	MOR-0251 / MORR-016-U1US	4529

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,228	GRASSO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-66, 68-70, 73-78, 81-88, 91-99, 135, 136 and 139-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *64,65,68,75-77,83,84,88,93,94,97 and 139-150* is/are allowed.

6)☒ Claim(s) *62,63,66,69,70,73,74,78,81,82,85-87,91,92,95,96,98,99,135 and 136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 62-66, 68-70, 73-78, 81-88, 91-99, 135, 136 and 139-150 are pending and under consideration.

The rejection of claim 98 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's arguments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 62, 63, 66, 69, 70, 73, 74, 78, 81, 82, 85-87, 91, 92, 95, 96, 98, 99, 135 and 136 under 35 U.S.C. 103(a) as being obvious over Nicolaides et al (U.S. 6,808,894) in view of Borreback et al (Adv Drug Del Rev, 1988, Vol. 2, pp. 143-165) is maintained for reasons of record..

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Nicolaides teach the elements of the instant claims with regard to anti-sense inhibition of PMS2 and with regard to the administration of dominant negative PMS2 (column 3, lines 29-41, column 4, lines 1-10). Nicolaides et al teach restoring genetic stability to the host after selection of hybridoma cells with the desired traits (Example 5). Nicolaides et al do not teach obtaining an antibody producing cell by in vitro immunization, or the specific "removal" of the anti-sense nucleic acids..

Borreback et al teach that in vitro immunization has great advantages over conventional means of obtaining monoclonal antibodies because in vitro immunization require only small amounts of antigen, and has the potential to produce an antibody against an epitope that fails to provoke an antibody by conventional administration. Borreback et al teach that in vitro immunization can be used to make a human antibody because it bypasses the requirement for sensitizing patients (page 144 under "Summary").

It would have been prima facie obvious at the time that the invention was made to use hybridomas or antibody producing lymphocytes for the antibody producing cells of Nicolaides. One of skill in the art would have been motivated to do so by the teachings of Borreback et al on the advantages of producing antibodies by the method. It would have been further obvious that the hybridoma cells need not be maintained with the anti-sense nucleic acids after antibody formation has occurred. One of skill in the art would have been motivated to not continue the exposure of the hybridoma to the anti-sense nucleic acid because Nicolaides teaches the restoration of "genetic stability" of the hybridoma and because the anti-sense nucleic acids are

expensive and there is no need to continue the exposure of the hybridoma to the antisense nucleic acid once antibody secretion has occurred. Further Nicloaides teach the exposure of the cells to dominant negative inhibitor of PMS2 by an inducible expression vector and the restoration of genetic stability once a cell line is produced that contains the desired genetic alterations by removal of the inducers used to activate the promoter of the inducible vectors (column 36, lines 12-24). Thus it would be obvious to one of skill in the art to "remove" the chemical inhibitor of mismatch repair based on the teachings of Nicolaides.

It is noted that the phrase "wherein said antibodies having higher affinity for said antigen than antibodies produced by said parental hybridoma cells have an affinity for said antigen of at least about 1 X 10^7 M-1 to about 1 X 10^{14} M-1" and the phrase "wherein said hypermutated hybridoma cells that produce antibodies in greater titers than said parental hybridoma cells have a titer that is at least about 1.5-8-fold greater than the titer produced by said parental hybridoma cells" is not given patentable weight when comparing the claims to the prior art as it simply expresses the intended result of a process step positively recited, see MPEP 2111.04.

Applicant has attempted to disqualify the rejection under 103(c) stating that U.S. 6,808,894 cannot be cited as prior art in this instance under 103(c) since it and the present application are owned by the same corporate entity (reel/frame: 011690/0696 and reel/frame: 015301/0172). this has been considered but not found persuasive. Citing the Reel and Frame records of U.S. 6,808,894 and the instant application does not provide sufficient evidence that the '894 patent and the instant application were commonly owned at the time of filing..

The rejection of claims 62, 63, 66, 69, 70, 73, 74, 78, 81, 82, 85-87, 91, 92, 95, 96, 98, 99, 135 and 136 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,808,894 in view of Borreback et al (Adv Drug Del Rev, 1988, Vol. 2, pp. 143-165) and Yelton et al (Journal of Immunology, 1995, Vol. 155, pp. 1994-2004) is withdrawn in light of applicant's Terminal Disclaimer, filed July 15, 2009..

Claims 64, 65, 68, 75-77, 83, 84, 88, 93, 94, 97 and 139-150 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643